nitinol-based, self-expanding stents for the treatment of iliac lesions similar to those in this study. Core laboratories were utilized for independent confirmation of angiography and duplex ultrasound findings. All site reported MAEs were adjudicated by an independent Clinical Events Committee.

RESULTS For the BIOFLEX-I study of patients with iliac disease treated with the Astron stent, the primary endpoint was met. The 12-month composite endpoint of MAE was 2.1% (3/146) ($p<0.001$) 95 % CI [0.4%, 5.9%]. The 30 day mortality rate was 0.7% (1/146) 95 % CI [0.0%, 3.8%]. Target lesion revascularization (TLR) rates at 12 months were 1.4% (2/146) 95 % CI [0.2%, 4.5%], and 12-month index limb amputation was 0.0% (0/146) 95 % CI [0.0%, 2.5%]. The secondary endpoint of primary patency was 89.8% (115/128) 95 % CI [83.3%, 94.5%] at 12 months.

CONCLUSION The 12-month outcomes of the BIOFLEX-I study for the Astron stent in iliac indications demonstrate a low MAE rate, high primary patency, and a low rate of TLR. This supports the safety and efficacy of the self-expanding, nitinol stent for treatment of atherosclerotic lesions in the iliac arteries.

CRT-304

Drug Coated Balloon (DCB) Angioplasty Versus Conventional Angioplasty for the Treatment of the Superficial Femoral Artery and PI-Segment In Pad-Patients - Updated Interim Results Of The Freeride Study

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BACKGROUND The use of paclitaxel coated DCB during percutaneous transluminal angioplasty (PTA) treatment of the femoropopliteal lesions in PAD patients might result in a significant reduced restenosis rate. Thus, the FREERIDE study investigates the inhibition of restenosis by the FREEWAY DCB versus plain balloon (POBA) in the treatment of occluded or stenotic lesions in the superficial femoral artery (SFA) and popliteal arteries (PI segment).

METHODS 280 patients will be randomized either to FREEWAY DCB or to POBA in 23 centers worldwide. The primary endpoint is clinically driven target lesion revascularization rate (TLR) at 6 months. Secondary endpoints include late lumen loss and patency rate at 6 months, TLR at 12 and 24 months follow up (FU), improvement in Rutherford classification and Ankle-Brachial index (ABI) and MAE.

RESULTS Until today over 100 patients have been enrolled, over 80 of them completed the 6 month FU. At 6 months FU positive trends are observed for the TLR rate (7.1 % vs. 16.7 % after POBA) and MAE (7.1 % vs 23.4 % after POBA). Furthermore there are positive trends in the patency rate and in the improvement of Rutherford classification after FREEWAY PTA vs. POBA.

CONCLUSION The continuously updated interim results indicate that FREEWAY DCB might provide an advantage for angioplasty in SFA and PI-segment lesions. DCB might overcome the existing limitations in the treatment of peripheral disease.

CRT-305

Randomized Clinical Trial Favors the Use Of Drug-coated Balloons Over Plain Balloons for the Postdilatation of Nitinol Stents in the SFA and PI Segment to Lower Restenosis Rate

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BACKGROUND Stents are needed in up to 50 % of all peripheral interventions where PTA with plain or drug-coated balloons alone will not reopen the vessel sufficiently. Nevertheless, the restenosis rate of stents is still a major limitation of peripheral arterial interventions. Drug-coated balloons potentially overcome the problem of in-stent restenosis when used for postdilatation after primary nitinol stenting in the SFA and PI segment.

METHODS The Freeway Stent Study is a prospective, randomized, international trial started in 15 centers in Germany and Austria. 200 patients will be enrolled and randomized equally to primary nitinol stenting followed by either DCB (Freeway™) or plain balloon postdilatation. Primary endpoint is clinically driven target lesion revascularization (TLR) at 6 months, secondary endpoints include further clinical and safety evaluations like shift in Rutherford classification and ABI, LLL, patency rate and MAE.

RESULTS Over 170 patients have been enrolled to date, of which over 130 have finished the 6 months and 100 the 12 months follow-up. The results highly favor the use of Freeway™ DCB over plain balloon based on clinically driven TLR (only 2.9 % vs. 11.9 % at 6 months and 9.1 % vs. 18.0 % at 12 months). This is supported by a statistically significant better clinical outcome for PAD patients treated with DCB as postdilatation device regarding primary patency rate, ABI and Rutherford classification at six months.

CONCLUSION The use of DCB as postdilatation device is investigated in a new approach to decrease the restenosis rate after nitinol stenting in the SFA and PI segment. The latest interim results of the Freeway Stent Study show that DCB might significantly lower the in-stent restenosis rate in the treatment of PAD patients.

CRT-306

Particulates from Hydrophilic Coated Guiding Sheaths Embolize to the Brain

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BACKGROUND Peripheral vascular interventions frequently employ guiding sheaths with hydrophilic coatings raising the concern for the embolization of this material clinically as increasingly documented.

METHODS A peripheral stent and delivery system (SDS) were deployed in the iliac and/or carotid arteries of 23 Yucatan miniswine via femoral or carotid artery access. SDS were deployed through a Cook® Flexor Ansel Guiding Sheath with a hydrophilic coating (AQ® hydrophilic coating). In one non-stented control animal, only the guiding sheath was advanced. Animals were euthanized at 3, 30, 90 & 180 days post intervention and brains removed for histopathology. In addition, coating material from the surface of a non-deployed guiding sheath was examined microscopically.

RESULTS The coated guiding sheath was associated with intravascular accumulation of an amorphous, non-refractile, non-crystalline, and non-birefringent embolic foreign material in sections of porcine brain which, on H&E staining, appeared lightly basophilic and slightly stippled. Material was observed at all time points and in all major regions of the brain, involving 52% of all test animals, and in the non-stented control animal. The incidence of embolic material was higher (63%) with carotid access than femoral access (20%). Evidence of adverse effects related to embolized material was limited to a single incidence of focally extensive chronic infarction in one brain.

In vitro incubation of the coated guiding sheath was associated with progressive separation and sloughing of its hydrophilic coating. Microscopic assessment of the sloughed hydrophilic coating was interpreted to be morphologically consistent with the emboli observed in the brains of animals exposed to the coated guiding sheath.

CONCLUSIONS The hydrophilic coating of Cook® Flexor Ansel Guiding Sheaths sloughed and embolized to the brain during deployment in a porcine model. Based on the increased reporting of embolic events involving hydrophilic coatings of interventional devices, further monitoring, documentation, and consideration of the potential side-effects of this embolized material in clinical scenarios is warranted.

CRT-307

Gender Differences in Patients with Lower Extremity Peripheral Artery Disease Referred for Endovascular Intervention

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BACKGROUND Lower extremity peripheral artery disease (PAD) affects approximately 8 million people in the US. Endovascular intervention is frequently performed in patients with symptomatic PAD. However, gender differences in patients referred for endovascular intervention are not well defined.

METHODS We retrospectively analyzed 530 patients who were referred for peripheral angiography at a tertiary care center in 2013. Patients were followed up for a median of 11.3 months. Outcomes of interest included extent of disease on semi-quantitative peripheral angiography, type of procedural intervention, and target vessel revascularization.

RESULTS Of the 530 patients, 320 (60.4%) were men and 210 (39.6%) were women. Demographic and clinical characteristics are presented in Table 1. The majority of patients underwent endovascular intervention (men 76% vs women 80%, $p=0.29$). Outcomes of interest are presented in Table 2.

CONCLUSION In a contemporary cohort of patients referred for endovascular intervention, despite fewer clinical comorbidities in women, there were no significant gender differences in burden of PAD or procedural outcomes.